

Sal  
C2  
cont

that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of active compounds consists of primary particles having a diameter less than or equal to about 10 microns, said primary particles optionally being formed into agglomerates.

4. (Twice amended) The composition of claim 3, wherein said hormone is vasopressin, [a vasopressin polypeptide analogue] a biologically active analogue of vasopressin, desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), [a somatostatin polypeptide analogue] a biologically active analogue of somatostatin, [a gonadotropin agonist polypeptide analogue (GnRHa)] a biologically active analogue of gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

21. (Twice amended) A method for systemic administration of a pharmaceutically active polypeptide, comprising

providing a composition comprising a mixture of active compounds (A) a pharmaceutically active polypeptide, and (B) an enhancer compound which [is a non-waxy solid at room temperature and which] (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of the polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device; and

causing said patient to inhale said composition from a dry powder inhaler device; provided that at least 50% of the total mass of the active compounds, at the point the active compounds enter the respiratory tract of the patient, consists of particles having a diameter less than or equal to about 10 microns.

27. (Twice amended) The method of claim 26 wherein said hormone is vasopressin, [a vasopressin polypeptide analogue] a biologically active analogue of vasopressin, desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin